



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,457	06/27/2003	Jay Daulton	AB-233U5	6594

23845 7590 07/01/2005

ADVANCED BIONICS CORPORATION
25129 RYE CANYON ROAD
VALENCIA, CA 91355

EXAMINER

SAVAGE, JASON L

ART UNIT PAPER NUMBER

1775

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/609,457

Applicant(s)

DAULTON, JAY

Examiner

Jason L. Savage

Art Unit

1775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06-27-03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20040714.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 20050613.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1775

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to an article, classified in class 428, subclass 582.
- II. Claims 14-20, drawn to a method, classified in class 228, subclass 124.6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially different process such as by placing brazing material adjacent to the metal and ceramic members and allowing the braze to wick in between the parts as opposed to preplacing the braze between the parts to be joined and/or by performing the brazing under different heating and cooling conditions and atmospheres such as brazing in a reduced pressure inert gas containing atmosphere as opposed to performing the brazing and cooling in a vacuum.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Peter Johnson on 6-13-05 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action.

Art Unit: 1775

Claims 14-20 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper.

Applicant has attempted to improperly incorporate by reference the disclosures of foreign patents WO 00/56394 in lines 9-10 of paragraph [0007] and WO 00/56677 in lines 14-15 of the same paragraph.

Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Applicant can also overcome the objection by removing the phrase “,which publication is incorporated herein by reference in its entirety,”.

Drawings

Figures 2A-5B and 8A-8B should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected

Art Unit: 1775

drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 1B contains reference number **234** which was not described in the specification. However, it is the position of the Examiner that this number refers to the grooves **324** such as is described in the specification in paragraph [0061].

In further support that this may be the case, reference number **324** pertaining to the grooves is not shown in the Figure 1B as was described in the specification in paragraph [0061].

The drawing objections would be overcome by amending Figure 1B wherein "**234**" was changed to **--324--**.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as

either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites that the metal member is an end cap to the ceramic member which completely closes the substantially close-ended end of the ceramic can. However, claim 1 upon which claim 3 depends recites that the metal member has exterior flanges having inner surfaces wherein said inner surfaces of the flanges adjoin the ceramic member at the formed end (emphasis added) of the ceramic member. Is it possible for the metal member to both function as an end cap to close an opening in the ceramic member while simultaneously having flange edges which are bonded to the formed portions of the ceramic? Applicant appears to be reciting two different metal member structures. The metal member structure of claim 1 being that which is depicted in Figures 6A and 6B wherein the external flanges **236B** of the metal member adjoin the formed ends **827** of the ceramic member. The metal member structure of claim 3

Art Unit: 1775

appears to be that which is depicted in Figures 9B-9C wherein the metal end cap **844** completely closes the end of the ceramic **845**.

Would the open ended portion of the ceramic depicted in Figure 9A be considered formed portions such as is recited in claim 1?

Claim 9 recites the same language as claim 3 and as such is also indefinite.

Claims 4-5 and 10-11 are dependent upon claims 3 and 9 respectively and further limit the end cap structure making them indefinite as well.

For the purposes of Examination, claims 3 and 9 have been considered as meaning:

"... wherein the ceramic member is a substantially close-ended ceramic can and a second [the] metal member forms an end cap to the ceramic member..."

Appropriate correction or clarification is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of copending Application No. 10/691,201 (see US Patent

Art Unit: 1775

Publication 2004/0088032). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 1 of the instant Application is exactly the same as claim 2 of Application 10/691,201 with the only exception being that claim 2 recites an electrode is attached to the claimed braze assembly. Since claim 1 of the instant Application recites comprising language, additional elements such as the electrode recited in claim 2 of Application 10/691,201 would not be excluded. Therefore, claim 1 of the instant Application is viewed as the "same invention" as that in copending Application 10/691,201.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-4 and 8-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 10/691,201 (see US Patent Publication 2004/0088032).

Although the conflicting claims are not identical, they are not patentably distinct from

Art Unit: 1775

each other because claim 2 of the copending Application recites the same braze assembly structure as is claimed in claims 1 and 8.

Regarding claims 2 and 8 of the instant Application, Claim 2 of copending Application 10/691,201 further includes the limitations that the electrode assembly is to be used with a microstimulator. Although the claims of copending Application 10/691,201 do not recite a shell of the microstimulator is hermetically sealed, the claimed braze assembly would form a hermetic seal wherein the sealed assembly is recited as being suitable for use as a microstimulator.

Regarding claims 3-4 and 9-10, although copending Application 10/691,201 does not specifically recite the electrode structure is used as an end cap structure, it would have been obvious to have used the electrode in such a capacity. Claims 4 and 10 of the instant Application reciting that the end cap is an electrode serve as further evidence that the use of the electrode in copending Application 10/691,201 would have been obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-8 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Byers et al. (US 4,991,582).

Regarding claim 1, Byers teaches a braze assembly comprising a metal member **18** including an exterior flange **64** of the metal member, a braze and a ceramic member **14** including a formed end **26**, wherein the formed end of the ceramic member **14** adjoins the inner surface of the exterior flange **64** and is brazed to the metal member with the braze material (Figure 9 and col. 7, ln. 54-68). Byers further teaches the braze is a titanium and nickel alloy (col. 4, ln. 66 – col. 5, ln. 9).

Regarding claims 2 and 8, Byers teaches the assembly is suitable for use in hermetically sealed housing shells for microstimulators (col. 1, ln. 7-18).

Regarding claims 6-7 and 12-13, Byers teaches the exterior flange **64** forms a step at the end of the metal member against which the formed end of the ceramic member may be received (Figure 9). Byers further teaches the surface area between the members is capable of receiving an adequate amount of braze material to form a strong braze bond (Figure 9 and col. 7, ln. 64-67). Byers also teaches the exterior flange **64** provides support to the braze assembly. Although Byers does not explicitly recite the support provided is lateral support, the flange structure of Byers would have has as much lateral support the assembly claimed by Applicant since Byers teaches the same structure which is claimed.

Claim Rejections - 35 USC § 103

Art Unit: 1775

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byers et al. (US 4,991,582) in view of Schulman et al. (US 6,208,894).

Byers teaches what is set forth above however it is silent to the ceramic member being substantially close-ended which has a metal end cap which completely closes the ceramic.

Schulman teaches an implantable device (col. 1, ln. 13-21) which comprises a braze assembly including a metal member **264** brazed to a ceramic member **260** (col. 12, ln. 41-67 and Figure 10A). Schulman further teaches that the ceramic member **260** is a substantially close-ended ceramic which is completely closed by an end cap electrode **112a** (col. 12, ln. 41-67 and Figure 10A). It would have been within the purview of one of ordinary skill in the art to have recognized that the metal flange containing, self-jigging, connection supporting microstimulator structure of Byers could have been used in a wide variety of known microstimulator devices with a reasonable expectation of success. It would have been obvious to one of ordinary skill in the art at the time of the invention to used the brazed assembly structure of Byers as the composite assembly in the microstimulator of Schulman in order to have formed a composite assembly which supports a firm connection between the ceramic and metal


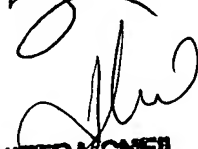
Art Unit: 1775

members. A microstimulator having been so modified would meet the claim limitation wherein the electrode end cap **112a** completely closes the ceramic member.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason L. Savage whose telephone number is 571-272-1542. The examiner can normally be reached on M-F 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on 571-272-1535. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jason Savage
6-23-05

JENNIFER MCNEIL
PRIMARY EXAMINER